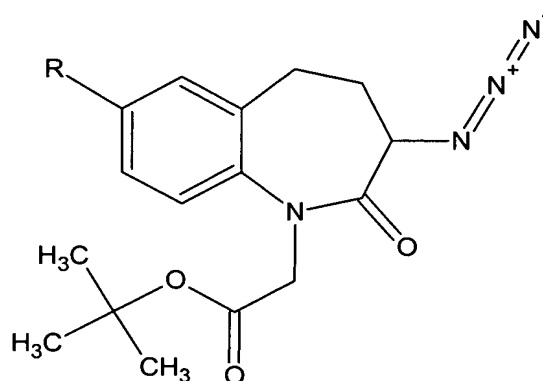


We Claim:

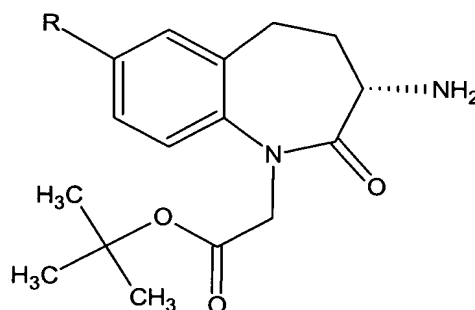
1. (Original) A process for preparation of highly pure 3-amino t-butyl ester of Formula II wherein R is hydrogen having no detectable quantity of impurity 7-bromo-3-amino t-butyl ester of Formula IIa, wherein R is Br, wherein the process comprises:

a) hydrogenating 3-azido t-butyl ester of Formula IV containing up to about 8% of 7-bromo-3-azido t-butyl ester of Formula IVa in presence of a noble metal catalyst; and



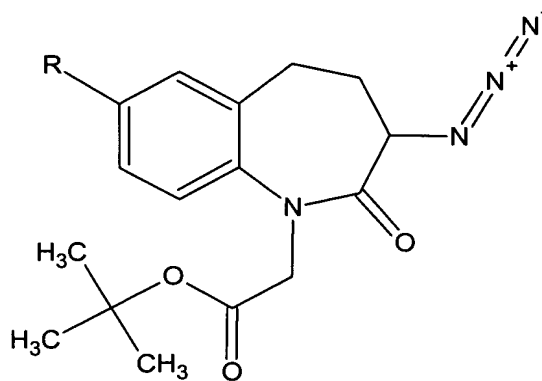
FORMULA IV (R = H)
FORMULA IVa (R = Br)

b) isolating highly pure racemic 3-amino t-butyl ester of Formula II having no detectable quantity of 7-bromo-3-amino t-butyl ester of Formula IIa

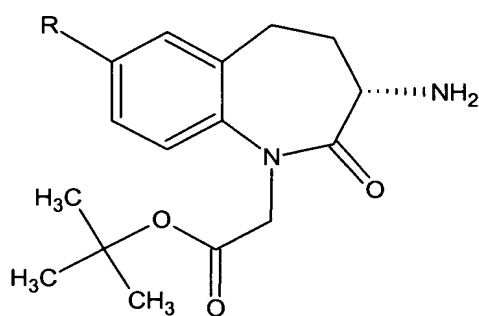


FORMULA II (R = H)
FORMULA IIa (R = Br)

- 1 2. (Original) A process according to claim 1 wherein the noble metal catalyst is
2 selected from a group comprising of palladium on carbon, platinum oxide,
3 platinum black, palladium acetate and rhodium on carbon.
- 1 3. (Original) A process according to claim 2 wherein the noble metal catalyst is
2 palladium on carbon.
- 1 4. (Original) A process according to claim 1 wherein hydrogen gas is used in
2 hydrogenation.
- 1 5. (Original) A process according to claim 1 wherein a source of hydrogen gas is
2 used in the reaction.
- 1 6. (Cancelled)
- 1 7. (Cancelled)
- 1 8. (Cancelled)
- 1 9. (Cancelled)
- 1 10. (Cancelled)
- 1 11. (Cancelled)
- 1 12. (Cancelled)
- 1 13. (Original) The process of claim 1, further comprising isolating the S-enantiomer
2 of the compound of Formula II by chiral resolution.
- 1 14. (Original) A process for preparation of highly pure 3-amino t-butyl ester of
2 Formula II having no detectable quantity of impurity 7-bromo-3-amino t-butyl
3 ester of Formula IIa, wherein the process comprises:
- 4 a) hydrogenating 3-azido t-butyl ester of Formula IV containing up to about 8%
5 of 7-bromo-3-azido t-butyl ester of Formula IVa in presence of Raney nickel to
6 get the racemic 3-amino t-butyl ester of Formula II containing up to about 8%
7 of 7-bromo-3-amino t-butyl ester of Formula IIa;



FORMULA IV (R = H)
FORMULA IVa (R = Br)



FORMULA II (R = H)
FORMULA IIa (R = Br)

- b) hydrogenating the product of step a) in the presence of a noble metal catalyst;
 and
- c) isolating highly pure racemic 3-amino t-butyl ester of Formula II having no
 detectable quantity of 7-bromo-3-amino t-butyl ester of Formula IIa.

15. (Cancelled)

16. (Cancelled)

17. (Cancelled)

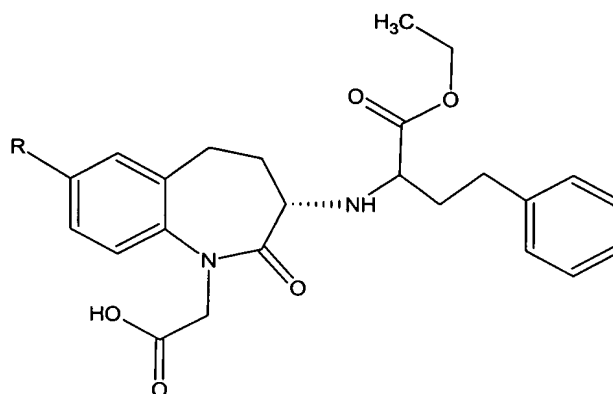
18. (Cancelled)

19. (Cancelled)

20. (Cancelled)

1 21. (Original) The process of claim 14, further comprising isolating the S-enantiomer
2 of the compound of Formula II by chiral resolution.

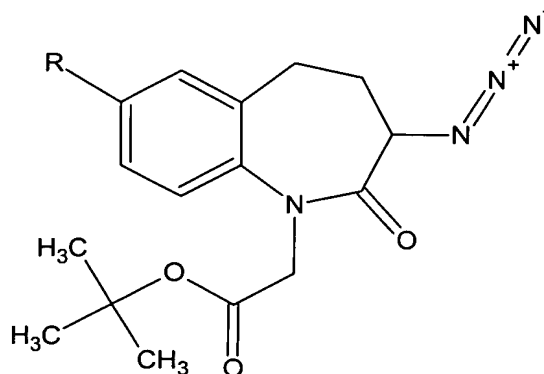
1 22. (Original) A process for preparation of highly pure benazepril of Formula I or a
2 pharmaceutically acceptable salt, solvate and hydrate thereof, having no detectable
3 quantity of 7-bromo analogue of Formula Ia, wherein the said process comprises of



5 **FORMULA I (R = H)**

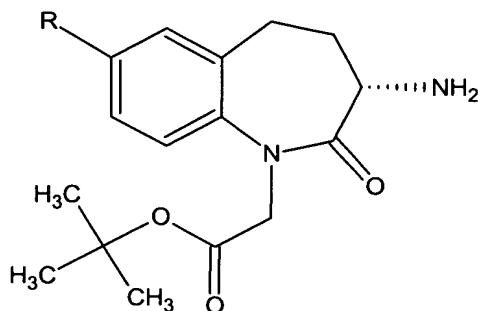
6 **FORMULA Ia (R = Br)**

7 a) hydrogenating 3-azido t-butyl ester of Formula IV, optionally containing up to
8 about 8% of 7-bromo-3-azido t-butyl ester of Formula IVa, in presence of a
9 metal catalyst and isolating the racemic 3-amino t-butyl ester of Formula II
10 which is optionally devoid of the corresponding 7-bromo-3-amino t-butyl ester
11 of Formula IIa impurity;



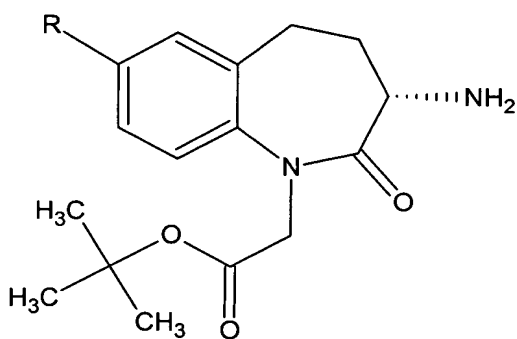
13 **FORMULA IV (R = H)**

14 **FORMULA IVa (R = Br)**

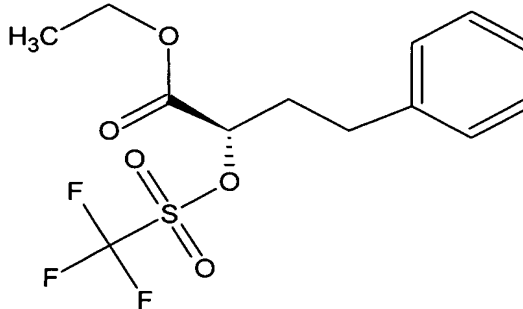


FORMULA II (R = H)
FORMULA IIa (R = Br)

- b) hydrogenating the racemic 3-amino t-butyl ester of Formula II, optionally containing up to about 8% of 7-bromo-3-amino t-butyl ester of Formula IIa, in presence of a noble metal catalyst to get highly pure racemic II having no detectable amount of 7-bromo ester of Formula IIa;
- c) converting the highly pure racemic 3-amino t-butyl ester of Formula II to the highly pure (S)- 3-amino t-butyl ester of Formula II by chiral resolution;
- d) condensing the highly pure (S)- 3-amino t-butyl ester of Formula II with Trifluoromethane sulphonic ester of ethyl (R)-2-hydroxy-4-phenylbutyrate of Formula III in presence of an organic solvent and a base to get highly pure compound of Formula I or physiologically acceptable salts, solvates or hydrates thereof.



FORMULA II (R = H)



FORMULA III

23. (Original) A process according to claim 22 wherein metal catalyst in step a) is selected palladium on carbon, platinum oxide, platinum black, palladium acetate, rhodium on carbon or Raney nickel.

- 1 24. (Original) A process according to claim 22 wherein noble metal catalyst in step b)
2 is selected from palladium on carbon, platinum oxide, platinum black, palladium
3 acetate or rhodium on carbon.
- 1 25. (Original) A process according to claims 22 and 23 wherein step b) is not
2 performed if in step a) metal catalyst is selected from palladium on carbon,
3 platinum oxide, platinum black, palladium acetate and rhodium on carbon.
- 1 26. (Original) A process according to claims 22 and 23 wherein step b) is performed if
2 in step a) metal catalyst used is Raney nickel.
- 1 27. (Original) A process according to claim 22 wherein step c) provides a tartarate salt
2 of (S)-II which is then converted to (S)-II freebase.
- 1 28. (Original) A process according to claim 27 wherein the intermediate tartarate salt
2 of S-II is purified by crystallization.
- 1 29. (Original) A process according to claim 22 wherein the organic solvent used in
2 step d) is selected from chlorinated hydrocarbons.
- 1 30. (Original) A process according to claim 29 wherein chlorinated hydrocarbon is
2 selected from chloroform, carbon tetrachloride, methylene chloride, ethylene
3 bromide, ethylene chloride or mixtures thereof.
- 1 31. (Cancelled)
- 1 32. (Original) A process according to claim 22 wherein intermediate compound VI is
2 isolated after completion of reaction between highly pure S-II and III.
- 1 33. (Original) A process according to claim 32 wherein the intermediate compound VI
2 is further converted to highly pure I by treatment with acid.
- 1 34. (Original) A process according to claim 33 wherein the acid used is mineral acid
2 or an organic acid.
- 1 35. (Cancelled)

- 1 36. (Original) A process according to claim 22 wherein the physiologically acceptable
2 salt of I is hydrochloride salt.
- 1 37. (Original) A highly pure compound of Formula II having no detectable quantity of
2 IIa.
- 1 38. (Original) A highly pure benazepril of Formula I or physiologically acceptable
2 salt, solvate and hydrate thereof having no detectable quantity of Ia.
- 1 39. (Original) A process of preparation of benazepril of Formula I or physiologically
2 acceptable salt, solvate and hydrate thereof wherein highly pure compound of
3 Formula II having no detectable quantity of IIa is used as an intermediate.
- 1 40. (Original) A pharmaceutical compositions comprising highly pure benazepril of
2 Formula I or physiologically acceptable salt, solvate and hydrate thereof having no
3 detectable quantity of Ia along with a pharmaceutically acceptable carriers or
4 diluents
- 1 41. (Original) A method of antagonizing angiotensin-converting enzyme (ACE)
2 wherein the said method comprises of administering to a mammal in need thereof
3 a therapeutically effective amount of highly pure benazepril of Formula I or
4 physiologically acceptable salt, solvate and hydrate thereof having no detectable
5 quantity of Ia.